PSJ3

Exhibit 631

PROJECT INITIATION FOR 5046 Suspicious Order Monitoring

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Approvals:

	Name:	***Date:***
Chair/Sponsor:	Wilson Lester	
Signature:		
Business Representative:	*Janet Hart*	
Signature:		
Business Representative:	*Sophia Lai*	
Signature:		
IS Representative:	*Karyn Kunzig*	
Signature:		

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Project Initiation Document

Background / Summary of the Project:

The purpose of this project is to develop effective controls against the diversion of controlled substances and conduct adequate due diligence to ensure that controlled substances distributed from the Distribution Centers are for legitimate patient needs. Rite Aid must ensure compliance with 21 U.S.C. 823 and/or C.F.R. 1307.74(b) to detect and report suspicious orders of controlled substances through the Distribution Centers.

Project Scope:

This project involves review of all sources of Pharmacy orders into the Distribution Centers. The Pharmacy Replenishment Order Review application will be modified to use separate override parameters for Controlled and Non-controlled Drugs. Controlled Drugs will be completely blocked from the Billing Manual Order Screens.

A portal application will be developed to identify potentially suspicious orders. DC personnel will contact the store and enter a reason code for the unusually high order quantity. Select reason codes will trigger follow up by ~~Loss Prevention~~ Government Affairs as well as a temporary block of overrides for this store.

Various reporting will be available to identify trends in order overrides, increased volume of controlled substance ordering, and repeated downward cycle counts. Both the DEA Audit Reports and Override Reason Code processing will be available on-demand for DEA inquiries.

No changes will be made to the actual Replenishment algorithms, McKesson Order process, Billing Allocations process, or WMS Systems.

Requirements:

Order Creation

[redacted]

Suspicious Order Review

Today blanket thresholds are manually enforced at 5,000 dosage units per individual NDC per week per store regardless of dispensing volume or trends. This is a labor intensive process with opportunity for order lines to be missed. In addition, stores which truly need this quantity must order it from McKesson. A new Billing application will be developed which will:

- [redacted]

Trending Reports

In addition to monitoring orders daily, the need exists to monitor ordering patterns of a store over time. A new Pharmacy Replenishment Reporting application will be developed which will:

- [redacted]

DEA Audit

A DEA Agent may request a store provide record of all Controlled Drugs carried in their store over a select period of time. Government Affairs contacts IS to create the report which contains total purchases, transfers, and sales by drug for that period of time. The report is sent to the PDM who must add the May 1st Audit Counts to the report as well as the ending count for the audit period. A new application will be developed which will:

- Allow the DEA Audit report to be requested on-demand.
- Require the store number, begin date, and end date of the transactions to be extracted.
- Include the May 1st Audit counts.
- Include the ending On Hand for the audit period. If no ending on hand count need the capability to enter a count on the audit manually.
- Provide the report on the Portal where it can be Exported to Excel for use by the PDM and store.
- Retain all data contained on this report for 2 years.

Assumptions:

- This process assumes that the DCs will pro-actively contact each store on the Suspicious Order Review screen.
- Corporate associates will not force distribute unreasonably large quantities of control drug items using the Merchandise Distribution or Pharmacy Replenishment Trend Adjustment applications.
- McKesson's systems contain sufficient controls to manage the DSD purchases.

Risks:

- Dedication of staff is critical to maintain the project schedule. Diversion of IS or Business team members will cause delays and a potential cost increase.

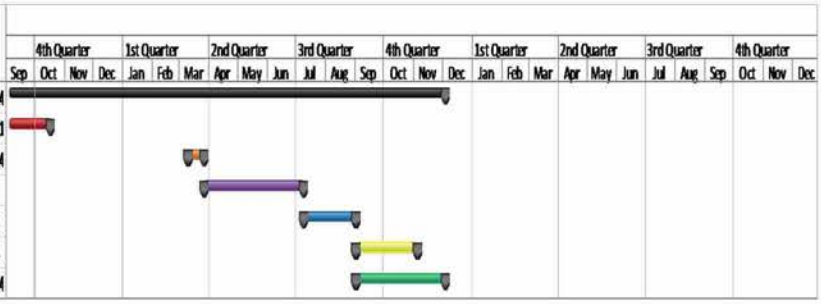
Interrelated Projects:

- This project is dependent upon the RX Tablet project due to IS Resource availability.

Time Line:

This timeline assumes Analysis will begin upon completion of the RX Tablet project. It may realistically begin earlier dependent on the timeline we receive from Dell for that project.

ID	% Compl	Task Name	Baseline Start	Baseline Finish
1	0%	Suspicious Order Monitoring	Wed 9/4/13	Wed 12/3/14
2	0%	Project Initiation	Wed 9/4/13	Wed 10/16/1
23	0%	Analysis	Mon 3/10/14	Wed 3/26/14
39	0%	Design	Thu 3/27/14	Tue 7/8/14
134	0%	Construction and Testing	Wed 7/9/14	Mon 9/1/14
187	0%	QA & BP Sign-off	Tue 9/2/14	Tue 11/4/14
197	0%	Installation	Tue 9/2/14	Wed 12/3/14



Cost Estimate:

Item	Internal Resource	External Resource	Non-Resource
Development Team			
Replen Order Limits	$87,320		
Trend Reports	$102,280		
Suspicious Order Review	$118,120		
DEA Audit	$97,880		
QA Team	$30,000		
Application Hardware			
Application Software			
Training			
Implementation			
Other			
Total	$435,600	$0	$0

Benefit Estimate:

<Complete the below benefits template or embed benefits spreadsheet template here.
Provide the Benefits template located in xxxxxxxxx to your Business Partner. When returned, save it in a network directory. Highlight and copy the spreadsheet cells to be included in this document.
In this document, click Paste, Paste Special, select Paste Link, select Microsoft Excel Worksheet Object, and click OK.
To refresh the sheet later if changes have been made, right click anywhere on the table, click Update Link.>

Recent DEA fines for controlled substance distributors have been tied to shipping suspicious orders to registrants (pharmacies)

- WAG $80,000,000 (DC DEA license surrendered)
- Cardinal Health $34,000,000 (DC DEA license surrendered)
- McKesson $13,000,000

McDowell County West Virginia recently filed suit (since withdrawn) against 3 Rite Aid Pharmacy locations and 3 Independent Pharmacies in the county for excessive sale of

opioid medications. Included in the suit was language concerning suspicious orders to the three Rite Aid pharmacies, how identified, how resolved and end outcome.

DEA has stated numerous times controlled substance distributors must have a protocol to identify and report suspicious orders based on individual pharmacy volume not generic limits for all registrants.

Controlled substance distributers must have a suspicious order monitoring system in place which can be provided to and explained to the DEA on any routine inspection/visit.

Project Team Stakeholders

	Name	Phone	Email
Chair Sponsor:	Wilson Lester	[redacted]	[redacted]
Business Representative:	Janet Hart	[redacted]	[redacted]
Business Representative:	Sophia Lai	[redacted]	[redacted]
Business Representative:	Rick Chapman	[redacted]	[redacted]
IS Representative:	Karyn Kunzig	[redacted]	[redacted]
Project Manager:			
Business Team:	DC Reps?		
	Steve Smith		[redacted]
	Scott Jacobson	[redacted]	[redacted]

Appendix A – Controllable Parameters

Parameter	Description	Value	Use
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

RITE AID

Project Initiation Document

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[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Appendix B – Reason Codes